



16-112

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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DATE: 20 November 2002

FROM/ATTORNEY: Dr. Mary M. Krinsky

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PHONE NUMBER: 203-773-9544

TO EXAMINER: Dr. Michael Borin

ART UNIT: 1631

SERIAL NUMBER: 09/867,914

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: A Petition for an Extension of Time (1 mo.) accompanies this response.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants	N.A. Williams, <i>et al.</i>
Serial No. - 09/867,914	Filing Date: May 30, 2001
Art Unit: 1631	Examiner: Michael Borin
Invention Title	Therapeutic Agents

#5/K.T.
11/21
ELECTION

Commissioner of Patents
and Trademarks
Washington, DC 20231

Reply to a Restriction Requirement Under 37 C.F.R. § 1.143

Dear Sir:

Please consider the remarks that follow, sent in response to a Restriction Requirement dated September 20, 2002, and grant the one month time extension requested in a Petition for Extension of Time Under 37 C.F.R. § 1.136(a) accompanying this response.

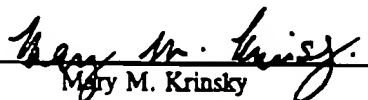
REMARKS

Claims 1 to 46 are pending in this application, which relates primarily to methods for treating diabetes and identifying agents useful in the treatment of diabetes.

In the above-referenced communication from the Patent Office, the Examiner required restriction under 35 U.S.C. § 121 between what were perceived as the following five groups of inventions:

I hereby certify that this correspondence is today being facsimile transmitted to the U.S. Patent Office's restriction election facsimile number for the art unit, 703-308-4315, on the date shown below.

November 20, 2002


Mary M. Krinsky

Group I (claims 1 to 9), drawn to methods for treating diabetes;
Group II (claims 10 to 12), drawn to pharmaceutical compositions;
Group III (claims 13 to 24, 43, and 44, drawn to methods for modulating the immune response;
Group IV (claims 25 to 30), drawn to assay methods; and
Group V (claims 31 to 42, 45 and 46), drawn to methods of preparing a medicament.

Applicants elect with traverse group II directed to pharmaceutical compositions. The requirement is traversed because applicants do not think the groups represent "separate and distinct" inventions required by 37 C.F.R. § 1.141 (a). A search of agents that are capable of modulating a ganglioside GM-1 associated activity that is mediated by intracellular signalling events useful in the treatment of diabetes should lead to the references applicable to all the groups, particularly as the subject matter has already been searched by the same Examiner during the prosecution of parent case U.S. serial number 08/999,458, filed December 29, 1997, which issued as U.S. Pat. No. 6,287,563 on September 11, 2001. Thus, the claims have "a community of properties justifying their grouping which [is] not repugnant to principles of scientific classification" [*In re Harnish*, 631 F.2d 716, 206 U.S.P.Q. 300, 305, (C.C.P.A. 1980)]. In general, an applicant is supposed to have a "right to define what he regards as his invention as he chooses, so long as his definition is distinct" [*ibid.*]. That court and its successors have long recognized the advantages to the public interest in permitting applicants to claim all aspects of the invention so as to encourage the making of a more detailed disclosure of all aspects of their discovery.

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112, all aspects of what they regard as their inventions, regardless of the number of statutory classes involved.

In re Kuehl, 177 U.S.P.Q. 250, 256 (C.C.P.A. 1973).

It shouldn't be an undue burden to examine the active ingredient useful in both compositions and methods, particularly, as mentioned above, this is a continuation-in-part application. On the other hand, requiring applicants to pay filing fees, prosecution costs, issue fees, and maintenance fees for multiple patents for one invention claiming human occludin is an undue burden for applicants, who qualify for small entity status. For these reasons, applicants respectfully request that the requirement for restriction be withdrawn.

If it is not, Applicants hereby petition the Commissioner to rejoin the method claims with the composition claims under the provisions of 37 C.F.R. § 1.141(b) and MPEP 821.04 when the composition claims are found to be allowable.

If the undersigned can advance the prosecution of the application in any way, she is invited to call the undersigned at the number set out below.

Respectfully submitted,

November 20, 2002



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